AUG 3 1 2005

510(k) SUMMARY

510(k) Notification K051405

GENERAL INFORMATION

Applicant:
CorMatrix Cardiovascular, Inc.
919 Waverly Road
Tallahassee, FL 32312
Phone: 850-508-0100
FAX: 850-383-1699

Contact Person:
Ms. Punam Gollamudi
Regulatory Project Manager
Experien Group, LLC
155 Moffett Park Drive, Suite A-101
Sunnyvale, CA 94089
Phone: 408-400-0856
FAX: 408-400-0865
Email: punam@experiengroup.com

Date Prepared:
July 18, 2005

DEVICE INFORMATION

Trade/Proprietary Name:
CorMatrix Pericardial Patch

Common/Classification Name/Product Code:
Product Code: DXZ
Device Classification Name: Patch, Pericardial

Device Classification:
Class II

PREDICATE DEVICES

- Cook Biotech, Inc., SurgiSIS (K980431)
- TEI Biosciences, Inc., TISSUEMEND (K020455)
- W.L. Gore & Associates, Inc., Preclude Pericardial Membrane (K012098)
- PM Devices, Inc., Peripatch Sheet (K031948)

INTENDED USE

The CorMatrix Pericardial Patch is intended for the reconstruction and repair of the pericardium.

PRODUCT DESCRIPTION

The CorMatrix Pericardial Patch is manufactured from porcine small intestinal submucosa (SIS) and is supplied in four (4)-ply sheets with varying dimensions.

SUBSTANTIAL EQUIVALENCE

The proposed indications for use for the CorMatrix Pericardial Patch are substantially equivalent to the indications for use of the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Thus, the CorMatrix Pericardial Patch is substantially equivalent to the predicate devices.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

Any differences in technological characteristics between the CorMatrix Pericardial Patch and the predicate devices do not raise any new issues of safety or efficacy. The performance and safety of the SIS material used in the CorMatrix Pericardial Patch was evaluated through extensive biocompatibility, bench and animal testing. The collective results have demonstrated that the CorMatrix Pericardial Patch is substantially equivalent to the respective predicate devices with regard to safety and efficacy.

SUMMARY

The CorMatrix Pericardial Patch is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2009

CorMatrix Cardiovascular, Inc.
c/o Ms. Punam Gollamudi
Regulatory Consultant
919 Waverly Road
Tallahassee, FL 32312

Re: K051405
CorMatrix Pericardial Patch
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac patch or pledget
Regulatory Class: II (two)
Product Code: 74 DXZ
Dated: July 18, 2005
Received: July 19, 2005

Dear Ms. Gollamudi:

This letter corrects our substantially equivalent letter of August 31, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Vechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051405

Device Name: CorMatrix Pericardial Patch

Indications For Use: The CorMatrix Pericardial Patch is intended for the reconstruction and repair of the pericardium.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K051405